Integrated Risk Information System (IRIS) & Operationalizing Pragmatic Systematic Review

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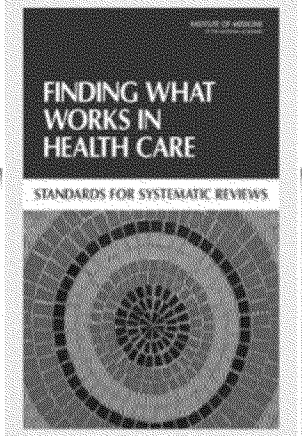
Systematic Review



A structured and documented process for transparent literature review[1,2]

"… systematic review is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent"

[1] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. EPA-HQ-OPPT-2016-0654. https://www.epa.gov/sites/production/files/2017-06/documents/prepubcopy_tsca_riskeval_final_rule_2017-06-22.pdf

[2] Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p.13-34. The National Academies Press. Washington, D.C. 2011

Why Should We Care?

- Increase transparency in our assessments
  - Flow of information
  - Document expert judgements
- Does NOT guarantee reproducibility in conclusions – there may be legitimate differences of expert judgments
- Pragmatic: Like it or not, systematic review is here to stay, e.g., increasingly "narrative" reviews are getting harder to publish in journals
- After initial learning curve, systematic review can be more efficient
  - Forces a focus on the key question(s)/evidence to address
  - Structured workflow facilitated by specialty software applications designed for collaboration
    - Project management efficiencies, matching of tasks with staff strengths
- I'm not convinced systematic review is more expensive or takes longer than a traditional review…

Key Elements of Systematic Review*

- **A clearly stated set of objectives (defining the question)**
- **Developing a protocol which describes the specific criteria and approaches that will be used throughout the process;**
- **Applying the search strategy criteria in a literature search;**
- **Selecting the relevant papers using predefined criteria;**
- **Assessing the quality of the studies using predefined criteria;**
- **Analyzing and synthesizing the data using the predefined methodology;**
- **Interpreting the results and presenting a summary of findings**

IRIS processes outlined in IRIS Handbook and assessment specific protocols

Notion of "predefined" needs to have an element of iterative when systematic review methods are applied to broad environmental health topics, BUT iterative decisions can still be documented with transparency

* Stephens (2016) The Emergence of Systematic Review in Toxicology. Toxicological Sciences. 152 (1): 10-16.

How is IRIS Operationalizing Systematic Review (SR)?

- **Full implementation of SR**
  - Compliance with SR reporting quality checklist and best practices
  - Processes outlined in IRIS Handbook and chemical-specific protocols
- **Modernize workflows and content management**
  - Through use of specialty software applications, machine learning, automation of workflows, template protocols
  - Enhance accessibility and data sharing through publicly available software platforms for assessments
  - Implementing program and project management tools to more effectively and efficiently utilize human resources to ensure timely delivery of products.
  - Utilizing a “train the trainer” approach on incorporating new workflows and software

All of the above more than meets NAS recommendations!

How is IRIS Operationalizing Systematic Review (SR)?

- **More frequent assessment of current and future agency chemical assessment needs**
  - e.g., an annual survey of needs to complement multi-year agenda
  - Identify candidates for rapid reviews, such as targeted updates to prior assessments
  - Develop assessment plans that define user needs, frame the scientific questions, and outline the evidence that will be collected prior to draft development
    - Work closely with agency program partners to ensure applicability of assessment
- **Systematic review Communities of Practice (CoP)**
  - Emma Lavoie (NCEA) and Kristan Markey (OSCP of OCSPP) co-organize
  - Monthly meetings – recently completed a survey of practices and needs
  - Shared usage and exploration of specialty software applications

Open Discussion